IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

REPLY MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO PARTIALLY MODIFY SCHEDULING ORDER

Immediately upon receipt of the Court's January 6, 2022 Scheduling Order ("January 6 Order" or "Order"), Dkt. No. 35, Defendant U.S. Food and Drug Administration ("FDA") began moving with utmost dispatch to marshal extraordinary resources—at the cost of an estimated five million dollars—to make every possible effort to comply with the unprecedented processing rate ordered by the Court in this matter. Notwithstanding these extraordinary efforts—and in contravention of the Court's explicit instruction that Plaintiff not advance conspiracies[1]—

[1] *See* Transcript of December 14, 2021 Scheduling Conference at 5:9-14 (APPX025) ("So, none of the political arguments, arguing against the administration for some—there being some big conspiracy when it comes to the vaccine … that's just not very helpful."); *id.* at 9 (APPX029) ("But the real thing I want to consider, let's figure out the best, quickest way to get these documents. And rather than arguing that the Government is trying to hide something or there's some big conspiracy here, that the green alien people want to inject us with something, is not going to be helpful[.]"); *compare, e.g.*, Opp. at 1 n.1 (illogically insinuating that FDA's policies for employee travel during an ongoing global pandemic "reflect [] issues with" and "cast[s] serious doubt on" the agency's decision to approve the Pfizer vaccine).

Plaintiff opposes FDA's motion on the baseless grounds that the agency "does not want independent scientists to review the documents it relied upon to license Pfizer's vaccine," Opp. at 1, and "does not intent [sic] to comply with the Order," *id.* at 14. The limited relief here sought by the agency, together with the extraordinary actions it is undertaking, refute these baseless contentions.

1. The instant motion is not seeking wholesale reconsideration of the Order. Rather, FDA is making a modest request that the Court afford it a brief "stand up" period to put the extraordinary resources it is actively gathering into place. During this period—and while the agency works simultaneously to bring a total of at least 23 full-time additional staff on to this project—FDA proposes to make monthly productions of 10,000 pages. Following this initial two-month "stand up" period (*i.e.*, after these additional temporary staff have been hired, onboarded, and trained) FDA would then be required to process 55,000 pages per month, beginning with its May 2, 2022, production until such time as production is complete. For all of the reasons given in its opening memorandum ("FDA Mem."), Dkt. No. 37, and in the sworn declarations that support it, FDA respectfully submits that this request is both eminently reasonable, and necessary to afford the agency a practical opportunity to achieve compliance with the Court's Order.

2. Plaintiff does not—and cannot—dispute that even the reduced "interim" production rate proposed by FDA is comparable to the most extreme instances cited in its briefing. *See* Dkt. No. 26 p. 23 (Plaintiff's second brief in advance of the scheduling conference, listing a small handful of outlier cases). Lacking any comparable cases to guide its arguments, Plaintiff instead stakes its opposition to a number of unfounded calculations premised on incorrect assumptions, and baseless accusations of bad faith. First, Plaintiff's math employs a 50-

pages-per hour rate that, for the reasons explained at length in the Weinfield Declaration, cannot be assumed to apply to FDA's FOIA reviews. *See generally* APPX015-019.

Second—and even more erroneously—Plaintiff also assumes that FDA can process all of the records contained within Pfizer's application at same rate at which it can process the case report forms ("CRFs"). *See* Opp. at 5-10. As explained in the FDA's opening memorandum, FDA agrees that the sections of the biological product file that do not contain any trade secret or confidential commercial information subject to FOIA Exemption 4—which FDA anticipates will include the CRFs—are less complex, and can therefore be processed more quickly (and by staff with less experience and technical expertise). FDA Mem. at 6 (explaining that FDA has asked Pfizer-BioNTech to identify those portions of the biological product file that do not contain any Exemption 4 information, and that once the FDA is in receipt of the vaccine sponsors' answer, the agency expects to be able to streamline its review of this subset of records).

3. Even by Plaintiff's own estimation, however, these files comprise roughly half of the overall biological product file. *See* Opp. at 6. And crucially, Plaintiff does not, and cannot, dispute that FDA's review of substantial *other portions* of the biological product file will require the much more complex task of reviewing the records at issue for trade secret and confidential commercial information. This review requires specialized training and experience, and is highly labor-intensive and time-consuming. *See* Weinfield Decl. at ¶ 13 (APPX018-109). Thus, Plaintiff's projections fail to account for the fact that, even by its own math (and also under FDA's proposed modification), FDA will complete processing of the CRFs after a few months.

While FDA is working to streamline review of these less complex records, the agency also recognizes that if it does not begin its work on the substantial portion of the biological product file that is significantly more complex now, it will be faced with an impossible task in a

few months' time. Accordingly, FDA is actively assessing how it can properly enlist the vaccine sponsors to speed the agency's review of the more complex portions of the biological product file as well. *See* FDA Mem. at 6. FDA expects to make an additional, specific request pertaining to certain portions of the biological product file to Pfizer by mid-February, and anticipates that these further coordination efforts will lay crucial "advance groundwork" for future productions of more complex materials. The brief "stand up" period requested by FDA is thus also in furtherance of its intention to "dual-track" the complex portions of the biological product file simultaneously with its streamlined review of the CRFs.

4. Plaintiff also misses the point in asserting that "[t]he FDA does not need to review [any] documents for relevance because if a document is in the file, then it is relevant and responsive." Opp. at 5. But figuring out what is "in the file" involves time and effort. Plaintiff seeks all publicly releasable data from the biological product file, but that file includes "all data and information submitted with or incorporated by reference in any application for a biologics license, *[investigational new drug records ("IND's")] incorporated into any such application*, master files, and other related submissions." 21 C.F.R. § 601.51(a) (emphasis added). Thus, as FDA explained in prior briefing, Plaintiff's request will require the FDA to determine which portions of the IND have been incorporated into the approved BLA. *See generally* Dkt. No. 29 (Defendant's Reply Brief in Advance of Scheduling Conference) at 24-26; *id.* at 26 (quoting an email in which Defendant expressly explained to Plaintiff that this determination is quite technical, and will "require a substantial investment of time from FDA").

5. In sum, neither Plaintiff's groundless accusations nor its faulty assumptions undermine the presumption of good faith and regularity to which FDA is entitled, and which is fully warranted here. *Cf. SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991)

(agencies' FOIA declarations are accorded "a presumption of good faith, which cannot be rebutted by purely speculative claims"); *Dep't of State v. Ray,* 502 U.S. 164, 179 (1991) (emphasizing that courts "generally accord Government records and official conduct a presumption of legitimacy"); *United States v. Chem. Found.*, 272 U.S. 1, 14-15 (1926) ("The presumption of regularity supports the official acts of public officers, and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties."). FDA is not trying to hide anything.[2] It has already published online hundreds of pages of the records most relevant to a review of FDA's approval decision, including many FDA review memos. Kotler Decl. ¶¶ 11-14. It has also, *inter alia*, already released to PHMPT in this litigation sections of the BLA that summarize the relevant safety and effectiveness data, including, the "Clinical Overview," the "Summary of Clinical Efficacy," and the "Summary of Clinical Safety." First Burk Decl. ¶ 27. And the agency is actively taking extraordinary and unprecedented steps to marshal every possible resource to comply with the Court's Order.[3]

Accordingly, for the reasons stated above, as well as those explained in detail in the agency's opening memorandum, FDA respectfully requests that the Court grant the instant motion and enter the requested relief.

Dated: January 27, 2022

Respectfully submitted,

BRIAN M. BOYNTON

[2] Nor is FDA "scared" of releasing non-exempt data and information from biological product files generally. FDA routinely releases in response to FOIA requests analyses of vaccine data and/or the publicly releasable information and data submitted by sponsors to support BLA approval.

[3] In its opposition brief, Plaintiff suggests that FDA should be required to produce records at a rate of 180,000 pages per month. Opp. at 14-15. Because it was not raised in a motion (*see* Fed. R. Civ. P. 7(b)(1)) and for all the reasons discussed in this reply brief as well as agency's opening memorandum, FDA opposes this suggestion.

Acting Assistant Attorney General
Civil Division

ELIZABETH J. SHAPIRO
Deputy Director
Federal Programs Branch

/s/ Antonia Konkoly
ANTONIA KONKOLY
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Room 11110
Washington, D.C. 20005
Tel: (202) 514-2395
Email: antonia.konkoly@usdoj.gov

Counsel for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on January 27, 2022, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

/s/ Antonia Konkoly
ANTONIA KONKOLY
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Room 11110
Washington, D.C. 20005
Tel: (202) 514-2395
Email: antonia.konkoly@usdoj.gov